

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

27 APR 2016

MEMORANDUM FOR AFMOA/HCE

ATTN: ELSA CAMOU/ COL MARK PACKER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- Your paper, entitled <u>HCE Research Coordination Directorate (ReCoorD Database)</u> presented at/published to <u>DHA Public Health Subcommitte Report</u> with MDWI 41-108, and has been assigned local file #<u>16154.</u>
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

hinda Steel-Goodan

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigations & Research Support

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5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)									
6. TITLE OF MATERIAL TO BE PUBLISHED	OR PRESENTED:			-					
HCE Research Coordination Directorate	(ReCoorD Database)								
7. FUNDING RECEIVED FOR THIS STUDY?									
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: YES NO									
9. IS THIS MATERIAL CLASSIFIED? YES NO									
10. IS THIS MATERIAL SUBJECT TO ANY LE AND DEVELOPMENT AGREEMENT (CRADA) ☐ YES NO NOTE: If the answer is YES	S then attach a copy of the	ne Agre	ement to the Publications/F	CITIAL DOODE	DTV DICUT	C ACDECHICUT CTO A			
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DEPARTMENT OF DEFENSE HEARING CENTER OF EXCELLENCE

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PURPOSE/RATIONAL

- Research project management ought to be considered an essential part of any effort, by departmental administrator and funding sponsor alike.
- mission scopes and visibility into those portfolios is often limited at Auditory portfolio management is often hidden within broader
- Current specialty-specific tracking databases do not exist
- Current broad-sweeping portfolio management tools do not exist (not true – define terms?)
- reports on the current state of "project-through-portfolio" efforts. The HCE receives requests from a variety of oversight bodies for
- Tools such as NIH's eReporter, while still in development, do not yet appear to meet HCE element requirements.

HCE TASKS

- Create a simple (Access) database to track, quantify and report on the auditory vestibular portfolio across the DOD
 - HCE HQ, Database Engineer will provide IT/IM support
- Vestibular Research Network (CAVRN). Efforts to be conducted by already embedded HCE Regional Coordination Team (RCT) Execute MOAs as requested by sites in the Collaborative Auditory members.
- Site Identifiable Information (SII) definition and handling instructions. Site-specific data may only be shared by HCE in an unidentified format (shared in DoD-wide/aggregate), unless shared with specific awareness and approval from said site.
 - MOA for each site defines HCE RCT responsibility and accountability for the data and its usage
- MOA is optional based on site preferences

ACCESSIBILITY/PROTECTION

- Access will be limited to the Regional Research Coordinator at each site and HCE HQ, with each RCT member populating only their location's version of the database back-end file.
- Data from each location will be uploaded to a central HCE database on a regular basis monthly
- HCE database administrator marries all backend files to one master HCE file, cleans any duplicates or errors and send regional team members back their own single-site back-end file to continue populating.
- RCT members will never see their counterparts' files.

REPORTING

- Reports collating data points for overview-level information dissemination will be generated by HCE HQ.
- Proprietary information or collected study data will never be included in ReCoorD

Reporting capability examples:

- Descriptive categorical data
- e.g., # "Diagnostic," # "6.2", or # "TRL 4" Tinnitus projects started/completed in FY15, etc.)
- Economic Data:
- e.g., total FY dollars applied for in intramural/NIH/NSF/VA/etc. grant funding vs. total awarded
 - These figures may be reported by category but not by site (i.e., \$10M Diagnostic or \$10M 6.2 PE projects or \$10M TRL 4 projects, etc.)
 - Site administration tools such as event dates approaching, including conference abstracts, grant submission and reporting, and annual IRB review deadlines.
 - Increases in collaboration, interdisciplinary make-up, success rates, translational pathways, gaps analysis, etc.

INFORMATION COLLECTED

NIH eReporter

Projects: title, description, start/end date

Persons: name, degrees, phone numbers, email

Organizations: grant-recipient organization only

CRADA/ MOAs: not reported

Data Sources: not reported

Grants/Proposals: ID#, funding agency, funding mechanism, award amount, award type, activity code

IRB: not reported

Protocol: clinicaltrials.gov ID#

Analysis not reported

Dissemination: publications found in PubMed and patents

ReCoorD

Projects: title, description, category (e.g., diagnostic, prevention, rehabilitation), relevance to other injuries (e.g., TBI, PTSD)

Persons: name, degrees, requirements (i.e., CITI training), phone numbers, email

Organizations: all engaged or collaborating

CRADA/MOA/MOU: Start date, ID #, parties, \$ value, status, execution & expiration dates

Data Sources: list of all data sources used, Data Sharing Agreements information (Start date, ID #, parties, \$ value, status, execution & expiration dates)

Grants/Proposals: ID#, funding agency, funding mechanism, submission date, award amount, award date

IRB: name of IRB, scientific reviewer, approval/renewal /closure dates

Protocol: title, start/end dates, subject target count, current enrollment, clinicaltrials.gov ID# if applicable

Analysis status

Dissemination: patents, publications, presentations, posters, reports

Information on grant-associated products including publications and patents for NIH grants

Data exports available via EXPORTER Free service

ReCoorD

- Monthly updates assured accuracy and completeness by HCE RCT
- Unique data captures
- characteristics specifically important to DOD (TRL, RDT&E program element category) for progression of the translational pathway and portfolio analysis
- characteristics specific to audiological/vestibular research for trends in evolution of new medical concepts
 - timelines for events along the project progression to identify/address bottlenecks and track progress
- Non-federally funded research (GME research, sponsored projects)
- Reporting capabilities across full database
- Utilizes Access system; user friendly, common competency, COTS product, DOD approved software
- HCE can use RePORTER's EXPORTER to download queries and upload into Access for cross-analysis.
 - Can also roll in and capture DOD extramural investments not using RePORTER.

Requires self-report from investigators

- Guidelines for reporting not always followed
- Expect entry gaps within and across projects
 - Timeliness of entry may vary
- Does not yet capture DOD; will not capture nor audiologyspecific elements
- No analytical tools included/available
- Not all federal agencies use this
- will not be comprehensive of all DOD RDT&E funding Timeline for DOD coming online is unknown; likely lines across services
 - Does not capture VA funding data
- investigators, knowledge product outcomes beyond PubMed No record of non-funded submissions, non-federally funded projects, project status, collaborating organizations or

- first 6 sites (highest output of DOD intramural research) are online Requires MOAs with collection sites within the CAVRN, and thus a phased implementation approach over a 3 year period. Only the and have populated the database.
 - Human resources ((1) 0.05 FTE HCE DBA and (7) 0.05 RCT members) are required
- DOD research execution only, at this time. Roll in of VA portfolio data is pending MOA.